IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC., PINNACLE HIP IMPLANT PRODUCT LIABILITY LITIGATION Steve Lawson , Plaintiff, vs. DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC. , DEPUY INTERNATIONAL, LTD. JOHNSON & JOHNSON JOHNSON & JOHNSON SERVICES, INC. Defendants.	Cause No. 3:11-MD-2244-K JURY TRIAL DEMANDED **3:cv-16-835**

COMPLAINT

COMES NOW Plaintiff Steve Lawson (hereinafter referred to as "Plaintiff"), by and through his attorney, and alleges of Defendants DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL, LTD., JOHNSON & JOHNSON and JOHNSON & JOHNSON SERVICES, INC. (hereinafter collectively referred to as Defendants) as follows:

I. PARTIES

1. Plaintiff Steve Lawson (hereinafter individually referred to as "Plaintiff") is a citizen of the State of Missouri and resides in Missouri.
2. On information and belief, Defendant DePuy Orthopaedics, Inc. (hereinafter individually referred to as "DePuy Orthopaedics") is a corporation organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. DePuy Orthopaedics designed, manufactured, and sold the hip implant that is the subject of this lawsuit.
3. Upon information and belief, Defendant DePuy Products, Inc. (hereinafter individual referred to as "DePuy Products" is a corporation organized and existsing under the laws of Indiana with its principal place of business in Warsaw, Indiana. DePuy Products designed, manufactured, and sold the hip implant that is the subject of this lawsuit.
4. On information and belief, Defendant DePuy International Limited (hereinafter individually referred to as "DePuy International") is a corporation organized and existing under the laws of United Kingdom with its principal place of business in Leeds, United Kingdom, and is an affiliate of defendant DePuy Orthopaedics, Inc. DePuy International designed, manufactured, labeled, marketed and sold the hip implant that is the subject of this lawsuit.
5. On information and belief, Defendant Johnson & Johnson (hereinafter individually referred to as "J&J") is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. As DePuy Orthopaedics's parent company, J&J designed, manufactured, marketed, and sold the hip implant that is the subject of this lawsuit. J&J also caused the DePuy Pinnacle Hip Implant to be marketed, sold, and distributed under its trademark, thereby indicating to consumers and doctors that it was the source of the Pinnacle Hip Implant.

6. On information and belief, Defendant Johnson & Johnson Services, Inc. (hereinafter individually referred to as "J&J Services") is a corporation organized and existing under the laws of New Jersey with its principal place of business in Piscataway, New Jersey. J&J Services distributed and sold the hip implant that is the subject of this lawsuit.

II. JURISDICTION

7. This Court has jurisdiction over this action under 28 U.S.C. §1332(a)(1) because Plaintiff and the Defendants are citizens of different states and the amount in controversy exceeds Seventy Five Thousand Dollars ($75,000.00).

8. The events described herein occurred in Boone County, Missouri, within the geographic jurisdiction of this Court.

III. VENUE

9. Venue is proper in the U.S. District Court, Western District of Missouri because the events or omissions giving rise to this claim occurred in that district. Pursuant to this Court's order, this case is filed into this Multi-District Litigation as a direct filing subject to transfer to the Western District of Missouri.

IV. INTRODUCTION AND SUMMARY OF ACTION

10. Defendants manufactured and/or imported the Pinnacle Hip Implant Device ("Pinnacle Device"). DePuy launched the Pinnacle Acetabular Cup System in 2001. The pinnacle Device was designed, developed and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion.

Defendants marketed the Pinnacle Device as having significant advantages over other hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you-and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

11. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

12. On information and belief, Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip Components are still in use today."

13. On information and belief, Plaintiff allege that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

14. On information and belief, Plaintiff alleges that Defendants are aware that use of Pinnacle Devices may result in metallosis, biologic toxicity, and high failure rate. Plaintiff further alleges that thw Pinnacle Device resulta in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiff further allege that Defendants are aware that metal particles from the Pinnacle Device result in metallosis, tissue death, bone erosion, and development of tumors.

15. On information and belief, Plaintiff alleges that particulate debris from the Pinnacle Device causes severe inflammation, severe pain, tissue and bone loss and other related diseases.

16. Plaintiff further alleges that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

V. FACTUAL ALLEGATIONS

A. The Pinnacle Device With an "Ultamet" Liner

17. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates with the curved surface of the acetabulum.

18. The Pinnacle Device is made up of four components: the metal femora stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates with the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces-the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium metal.

B. Defendants Did Not Seek Premarket Approval From the FDA, and Thus the FDA Made No Finding That the Pinnacle Device is Safe or Effective

19. The Pinnacle Device is a Class III medical device. Class III Device are those that operate to sustain human life, are of importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

20. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical Devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

21. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant, a full statement of the device's components, ingredients, and properties and of the principle or principles of operation, a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such Device; samples or device components required by the FDA; and a specimen of the proposed labeling.

22. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

23. A medical Device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket

approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e. a device approved prior to May 28, 1976). This exception to premarket approval is know as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

24. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another, older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

25. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

C. Defendants Took No Steps To Test The Pinnacle Device Or They Would Have Discovered That It Leads To Metallosis And Other Complications Before Releasing It On The Market.

26. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007, that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to

the release of metal particles in the patients' surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

27. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patients' tissue surrounding the implant, giving rise to metallosis, pseudotumors, or other conditions.

28. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

29. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of the ASR XL Acetabular System. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall Pinnacle Device for the same reasons.

30. On information and belief, Plaintiff alleges that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

31. On information and belief, Plaintiff alleges that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times

higher than acceptable or recommended safety levels. Notably, the same physician, Thomas Schmalzried, M.D, designed the ASR XL Acetabular System and the Pinnacle Device.

32. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, the Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

33. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendant's metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

34. Despite the public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

35. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patient's with an unreasonably high percentage of those patient's being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need

for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

D. Plaintiff Was Implanted With a Pinnacle Device And As A Result Was Required To Undergo Revision Surgery Due to Metallosis And Other Complications

36. On or about [May 7, 2009, Plaintiff underwent a right total hip arthroplasty procedure. A Pinnacle Device with an Ultamet liner was implanted in place of his right hip. Over time the known and common problem of natural and biologic corrosion and friction wear caused large amounts of toxic cobalt-chromium metal ions and particles to be released in Plaintiff's blood and tissue and bone surrounding the implant.

37. After implantation of the Pinnacle Device, Plaintiff began experiencing severe pain and discomfort and inflammation in his right thigh, buttocks, hip area and groin and other problems.

38. Due to Plaintiff's chronic pain and discomfort and other symptoms, Plaintiff underwent revision surgery on or about March 5, 2015. The Pinnacle Device had caused a significant amount of metal debris or metallosis to accumulate within the hip capsule and in the soft tissue surrounding the right implant, and a great deal of inflammation.

39. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in his total hip arthroplasty.

40. Plaintiff was unaware of any causal link between the injuries [he or she] has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff first became aware of said causal link when [he or she] became aware of the recall of the ASR. Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Pinnacle Device' defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

VI CLAIMS FOR RELIEF

COUNT I
(Strict Product Liability – Failure to Warn)

41. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

42. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Pinnacle Device and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Pinnacle Device.

43. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her physician, of the true risks of the Pinnacle Device, including that the Pinnacle Device was prone to excessive metal wear, and that the metal wear particles could cause inflammation and tissue and bone damage and that the acetabular cup could loosen and

separate from the hip socket, causing severe pain and injury, and requiring further treatment, including revision surgery and/or replacement.

44. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Pinnacle Device. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Pinnacle Device and no patient, including Plaintiff, would have had the Pinnacle Device implanted.

45. Defendants failed to provide timely and reasonable instructions and training concerning safe and effective use of the Pinnacle Device to either Plaintiff or his physician.

46. The Pinnacle Device, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Pinnacle Device.

47. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

48. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems

appropriate.

COUNT II
(Strict Product Liability – Design Defect)

49. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

50. Defendants are the researcher, developer, manufacturer, importer, distributor, marketer, promoter, supplier and seller of the Pinnacle Device, which is defective and unreasonably dangerous.

51. The Pinnacle Device is defective in its design or formulation in that it is not reasonably fit, suitable or safe for it intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The DePuy Pinnacle Device is defective in design in that it lacks efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses.

52. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Pinnacle Device did not outweigh its risks.

53. The defective condition of the Pinnacle Device rendered it unreasonably dangerous and/or not reasonably safe, and the Pinnacle Device was in this defective condition at the time it left the hands of the Defendants. The Pinnacle Device was expected to and did reach Plaintiff and his physician without substantial change in the condition on which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

54. Plaintiff was unaware of the significant hazards and defects in the Pinnacle Device. The

Pinnacle Device was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Plaintiff used the Pinnacle Device, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the Pinnacle Device implanted it was represented to be safe and free from latent defects.

55. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the Pinnacle Device, which was unreasonably dangerous for its foreseeable uses because of its design defects.

56. Defendants knew or should have known of the danger associated with the use of the Pinnacle Device, as well as the defective nature of the Pinnacle Device, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the Pinnacle Device so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Pinnacle Device.

57. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT III

(Strict Product Liability – Failure to Adequately Test)

58. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if

fully set forth herein.

59. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

60. Defendants advised consumers that the Pinnacle Device was a safe and effective hip replacement device. Defendants failed to adequately test the Pinnacle Device to ensure that it would not fail early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

61. Had Defendants adequately tested the Pinnacle Device and disclosed the results of those tests to the public, Plaintiff would not have elected to have the Pinnacle Device surgically implanted.

62. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT IV
(Strict Product Liability – Design Defect)

63. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

64. Defendants designed, manufactured, tested, marketed and distributed into the stream of

commerce the Pinnacle Device.

65. Defendants made representations to consumers regarding the character or quality of Pinnacle Devices, including but not limited to statements that the Pinnacle Devices were a safe and effective hip replacement system. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles." Defendants also advertised that the Pinnacle Device is "[d]esigned for active lifestyles." They further asserted that the "DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering, research and expertise, we've created a total hip replacement solution that offers low wear and high stability." They further touted that "[w]ith DePuy Advance Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

66. The Pinnacle Devices placed into the stream of commerce by Defendants were defective in that, when they left the hands of Defendants, they did not conform to Defendants' representations.

67. Plaintiff justifiably relied upon Defendants' representations regarding the Pinnacle Device.

68. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems

appropriate.

COUNT V
(Negligence)

69. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

70. At all times herein mentioned Defendants had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, and sale of the DePuy Pinnacle Device to ensure that it would be safely used in a manner and for a purpose for which it was made.

71. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, advertising, marketing, and sale of the DePuy Pinnacle Device.

72. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Plaintiff and his physicians as to the risks of the DePuy Pinnacle Device.

73. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the DePuy Pinnacle Device when they knew or should have known of said risks.

74. Defendants owed a duty to Plaintiff to timely inform his orthopedic surgeon of the significant problems being experienced with the product. Defendants failed to advise patients like Plaintiff that monitoring of the DePuy Pinnacle Device was necessary to avoid a long and painful period, where the device failure would go undetected - as it did in this case.

75. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and punitive damages in an amount to be

proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT VI
(Breach of Implied Warranties)

76. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.
77. Prior to the time that the DePuy Pinnacle Device was used by Plaintiff, Defendants impliedly warranted to Plaintiff and his physician that the DePuy Pinnacle Device was of merchantable quality and safe and fit for the use for which it was intended.
78. Plaintiff and his physician were and are unskilled in the research, design and manufacture of the DePuy Pinnacle Device, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the DePuy Pinnacle Device.
79. The DePuy Pinnacle Device was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.
80. Defendants, by selling, delivering and/or distributing the defective DePuy Pinnacle Device to Plaintiff breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.
81. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained

severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [her or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT VII
(Breach of Express Warranty)

82. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

83. At all times herein mentioned, Defendants expressly warranted to Plaintiff and his physician, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned DePuy Pinnacle Device was safe, effective, fit and proper for its intended use.

84. In utilizing the aforementioned DePuy Pinnacle Device, Plaintiff and his physician relied on the skill, judgment, representations and foregoing express warranties of Defendants.

85. Said warranties and representations were false in that the aforementioned DePuy Pinnacle Device was not safe and was unfit for the uses for which it was intended.

86. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT VIII
(Consumer Fraud Act Violation)

87. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

88. At all times relevant to this action, the Missouri Merchandising Practices Act codified at §407.010, R.S.Mo, et seq., was in effect. Section 407.020 R.S.Mo., states, in relevant part, that:

> 4070.020.1. The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce … is declared to be an unlawful practice.

89. Defendants made misrepresentations and deceptive statements in connection with the marketing, promotion and sale of the DePuy Pinnacle Device in violation of the Missouri Merchandising Practices Act.

90. Defendants engaged in deceptive acts or practices in violation of the Missouri Merchandising Practices Act, including, but not limited to, utilizing deception, fraud and misrepresentation, and concealment, omission and suppression of data and adverse events reported to Defendants and the U.S. Food and Drug Administration (FDA) regarding the safety and efficacy of the DePuy Pinnacle Device, and the unreasonably dangerous nature of the DePuy Pinnacle Device. Defendants violated the Missouri Merchandising Practices Act by concealing, omitting and failing to inform Plaintiff and other purchasers of the high product

failure rate of the DePuy Pinnacle Device.

91. Defendants' deceptive acts and conduct occurred during a course of conduct involving trade or commerce.

92. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT IX
(Negligent Misrepresentation)

93. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

94. At the time Defendants manufactured, designed, marketed, sold and distributed the DePuy Pinnacle Device for use by Plaintiff, Defendants knew or should have known of the use for which the DePuy Pinnacle Device was intended and the serious risks and dangers associated with such use of this particular device.

95. Defendants owed a duty to treating physicians and ultimate end users of the DePuy Pinnacle Device, including Plaintiff, to accurately and truthfully represent the risks of the device. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff, the medical community and public about the risks of the DePuy Pinnacle Device, which Defendants knew or in the exercise of diligence should have known.

96. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT X
(Intentional Misrepresentation)

97. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

98. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the DePuy Pinnacle Device owed a duty to provide accurate and complete information regarding the DePuy Pinnacle Device.

99. Defendants' advertising and marketing program, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the DePuy Pinnacle Device was safe for human use, had no unacceptable side effects and would not interfere with daily life.

100. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the DePuy Pinnacle Device. Defendants, through promotional practices, deceived treating physicians, Plaintiff and the public. Defendants falsely and deceptively kept relevant information from treating

physicians, and the general public, including Plaintiff, regarding the safety of the DePuy Pinnacle Device.

101. Defendants expressly denied that the DePuy Pinnacle Device created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the device.

102. Defendants did not accurately report the results of adverse events to physicians and the public regarding DePuy Pinnacle Device failures while undertaking a major advertising campaign to sell the DePuy Pinnacle Device. Defendants received reports of the DePuy Pinnacle Device defects from various sources, while continuing to sell the device for implantation in individuals including Plaintiff.

103. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the DePuy Pinnacle Device.

104. Defendants possessed evidence demonstrating that the DePuy Pinnacle Device fails and/or malfunctions. Nevertheless, Defendants continued to market the DePuy Pinnacle Device by providing false and misleading information with regard to its safety to Plaintiff and his treating physicians.

105. Defendants engaged in all the acts and omissions described above with the intent that Plaintiff's physicians and Plaintiff would rely on the misrepresentation, deception and concealment in deciding to use Defendants' DePuy Pinnacle Device.

106. Plaintiff and his treating physician justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above. This reliance proximately caused the injuries as damages detailed herein.

107. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained

severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT XI
(Fraud)

108. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

109. At all relevant times during the course of dealing between Defendants and Plaintiff, Defendants misrepresented the safety and efficacy of the DePuy Pinnacle Device and represented that it was safe for its intended use.

110. Defendants intentionally, knowingly, and/or recklessly failed to disclose, among other things, the high failure rate of the DePuy Pinnacle Device it became apparent, as previously alleged.

111. Defendants were under a duty to disclose to Plaintiff, the medical community, and public, the defective nature of the DePuy Hip Implant and had full access to material facts concerning the defective nature of the DePuy Pinnacle Device and the propensity of the DePuy Pinnacle Device to fail, and hence, cause injuries to the patients who had the DePuy Pinnacle Device implanted in them.

112. Defendants' misrepresentations, concealment, suppression and omissions were made

purposefully, willfully, wantonly, uniformly, deliberately or recklessly to Plaintiff, the medical community, and the public, to induce the purchase and use of Defendants' DePuy Pinnacle Device over other hip replacement products available on the market and to induce patients to agree to have the DePuy Pinnacle Device implanted into their bodies. Plaintiff and his treating physician reasonably relied upon the misrepresentations and omissions made by Defendants about the DePuy Pinnacle Device when agreeing to purchase use and/or have the DePuy Pinnacle Device implanted.

113. Defendants knew that Plaintiff, other consumers and treating physicians had no way to determine that Defendants' misrepresentations and omissions concerning the DePuy Pinnacle Device were false and misleading.

114. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT XII
(Constructive Fraud)

115. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

116. At the time Defendants sold the DePuy Pinnacle Device to Plaintiff, Defendants were in a

unique position of knowledge concerning the safety and effectiveness of the DePuy Pinnacle Device, which knowledge was not possessed by Plaintiff or his physicians, and Defendants thereby held a position of superiority over Plaintiff.

117. Through their unique knowledge and expertise regarding the defective nature of the DePuy Pinnacle Device, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff that they had knowledge of the truth of the representation that the DePuy Pinnacle Device was safe and effective for its intended use and was not defective.

118. Defendants' representations to Plaintiff, the medical community, and the public were unqualified statements made to induce Plaintiff and his physician to purchase and use the DePuy Pinnacle Device; and Plaintiff and his physician relied upon the statements when purchasing the device and having it implanted into her body.

119. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with him. Plaintiff reasonably relied on Defendants' representations.

120. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT XIII
(Negligent Infliction of Emotional Distress)

121. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

122. Defendants carelessly and negligently manufactured, marketed and sold the DePuy Pinnacle Device to Plaintiff, carelessly and negligently concealed the DePuy Pinnacle Device defects from Plaintiff, and carelessly and negligently misrepresented the quality, safety and usefulness of the DePuy Pinnacle Device.

123. Plaintiff was directly involved in and directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained severe physical injuries, economic losses, and other damages as a direct result of his decision to use and have implanted in his body a defective and dangerous product, manufactured, sold and distributed by the Defendants.

124. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which [he or she] is entitled to compensatory and punitive damages in an amount to be proven at trial.

WHEREFORE, Plaintiff prays for judgment against Defendants in a monetary amount in excess of Seventy Five Thousand Dollars ($75,000.00) that is fair and reasonable to compensate him for his injuries, together with his costs of court and for such further relief as the Court deems appropriate.

COUNT XIV
(Exemplary Damages)

125. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

126. Defendants, and each of them, showed a complete indifference to or reckless disregard for the safety of others, and Plaintiff in particular, when they knew of the defective and unreasonably dangerous product as set forth above.

WHEREFORE, for the reasons stated above, Plaintiff prays for judgment against Defendants in an additional amount sufficient to punish said defendants and dissuade them and others from like conduct, for costs of suit and for such other relief as this court deems just and proper.

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